#### 118TH CONGRESS 1ST SESSION

# S. 1339

To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.

# IN THE SENATE OF THE UNITED STATES

April 27, 2023

Mr. SANDERS (for himself, Mr. CASSIDY, Mrs. MURRAY, and Mr. MARSHALL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

# A BILL

- To provide for increased oversight of entities that provide pharmacy benefit management services on behalf of group health plans and health insurance coverage.
  - 1 Be it enacted by the Senate and House of Representa-
  - 2 tives of the United States of America in Congress assembled,
  - 3 SECTION 1. SHORT TITLE.
  - 4 This Act may be cited as the "Pharmacy Benefit
- 5 Manager Reform Act".
- 6 SEC. 2. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-
- 7 MACY BENEFIT MANAGEMENT SERVICES.
- 8 (a) PHSA.—Title XXVII of the Public Health Serv-
- 9 ice Act (42 U.S.C. 300gg et seq.) is amended—

1	(1) in part D (42 U.S.C. 300gg-111 et seq.),
2	by adding at the end the following new section:
3	"SEC. 2799A-11. OVERSIGHT OF ENTITIES THAT PROVIDE
4	PHARMACY BENEFIT MANAGEMENT SERV-
5	ICES.
6	"(a) In General.—For plan years beginning on or
7	after January 1, 2025, a group health plan or health in-
8	surance issuer offering group health insurance coverage
9	or an entity providing pharmacy benefit management serv-
10	ices on behalf of such a plan or issuer shall not enter into
11	a contract with an applicable entity that limits the disclo-
12	sure of information to plan sponsors in such a manner
13	that prevents the plan or issuer, or an entity providing
14	pharmacy benefit management services on behalf of a plan
15	or issuer, from making the reports described in subsection
16	(b).
17	"(b) Reports.—
18	"(1) In general.—For plan years beginning
19	on or after January 1, 2025, not less frequently
20	than annually, an entity providing pharmacy benefit
21	management services on behalf of a covered group
22	health plan shall submit to the plan sponsor of such
23	covered group health plan a report in accordance
24	with this subsection and make such report available

to the plan sponsor in a machine-readable format

1	and, as the Secretary, the Secretary of Labor, and
2	the Secretary of the Treasury may determine, other
3	formats. Each such report shall include, with respect
4	to the covered group health plan—
5	"(A) as applicable, information collected
6	from drug manufacturers by such issuer or en-
7	tity on the total amount of copayment assist-
8	ance dollars paid, or copayment cards applied,
9	that were funded by the drug manufacturer
10	with respect to the participants and bene-
11	ficiaries in such plan;
12	"(B) a list of each drug covered by such
13	plan or entity providing pharmacy benefit man-
14	agement services that was billed during the re-
15	porting period, including, with respect to each
16	such drug during the reporting period—
17	"(i) the brand name, generic or non-
18	proprietary name, and National Drug
19	Code;
20	"(ii) the number of participants and
21	beneficiaries for whom the drug was billed
22	during the reporting period, the total num-
23	ber of prescription claims for the drug (in-
24	cluding original prescriptions and refills),
25	and the total number of dosage units of

1	the drug dispensed across the reporting pe-
2	riod;
3	"(iii) for each claim or dosage unit de-
4	scribed in clause (ii), the type of dis-
5	pensing channel used, such as retail, mail
6	order, or specialty pharmacy;
7	"(iv) the wholesale acquisition cost,
8	listed as cost per days supply, cost per dos-
9	age unit, and cost per typical course of
10	treatment (as applicable);
11	"(v) the total out-of-pocket spending
12	by participants and beneficiaries on such
13	drug after application of any benefits
14	under the plan or coverage, including par-
15	ticipant and beneficiary spending through
16	copayments, coinsurance, and deductibles,
17	but not including any amounts spent by
18	participants and beneficiaries on drugs not
19	covered under the plan or coverage or for
20	which no claim is submitted to the plan or
21	coverage; and
22	"(vi) for any drug for which gross
23	spending by the plan exceeded \$10,000
24	and that is one of the 50 prescription
25	drugs for which the group health plan

1	spent the most on prescription drug bene-
2	fits during the reporting period—
3	"(I) a list of all other drugs in
4	the same therapeutic class, including
5	brand name drugs and biological
6	products and generic drugs or bio-
7	similar biological products that are in
8	the same therapeutic class as such
9	drug; and
10	"(II) if applicable, the rationale
11	for preferred formulary placement of
12	such drug in that therapeutic class,
13	selected from a list of standard ra-
14	tionales established by the Secretary;
15	"(C) a list of each therapeutic class of
16	drugs that were dispensed under the health
17	plan during the reporting period, and, with re-
18	spect to each such therapeutic class of drugs,
19	during the reporting period—
20	"(i) total gross spending by the plan,
21	before rebates, fees, alternative discounts,
22	or other remuneration;
23	"(ii) the number of participants and
24	beneficiaries who filled a prescription for a
25	drug in that class;

1	"(iii) if applicable to that class, a de-
2	scription of the formulary tiers and utiliza-
3	tion management mechanisms (such as
4	prior authorization or step therapy) em-
5	ployed for drugs in that class;
6	"(iv) the total out-of-pocket spending
7	by participants and beneficiaries, including
8	participant and beneficiary spending
9	through copayments, coinsurance, and
10	deductibles; and
11	"(v) for each therapeutic class under
12	which 3 or more drugs are included on the
13	formulary of such plan—
14	"(I) the amount received, or ex-
15	pected to be received, by such entity,
16	from an applicable entity, in rebates,
17	fees, alternative discounts, or other
18	remuneration that—
19	"(aa) has been paid, or will
20	be paid, by such an applicable
21	entity for claims incurred during
22	the reporting period; or
23	"(bb) is related to utilization
24	of drugs or drug spending;

1	"(II) the total net spending by
2	the health plan on that class of drugs;
3	and
4	"(III) the net price per typical
5	course of treatment or 30-day supply
6	incurred by the health plan and its
7	participants and beneficiaries, after
8	rebates, fees, alternative discounts, or
9	other remuneration provided by an
10	applicable entity, for drugs dispensed
11	within such therapeutic class during
12	the reporting period;
13	"(D) total gross spending on prescription
14	drugs by the plan during the reporting period,
15	before rebates, fees, alternative discounts, or
16	other remuneration provided by an applicable
17	entity;
18	"(E) the total amount received, or ex-
19	pected to be received, by the health plan, from
20	an applicable entity, in rebates, fees, alternative
21	discounts, and other remuneration received
22	from any such entities, related to utilization of
23	drug or drug spending under that health plan
24	during the reporting period;

1	"(F) the total net spending on prescription
2	drugs by the health plan during the reporting
3	period;
4	"(G) amounts paid directly or indirectly in
5	rebates, fees, or any other type of compensation
6	(as defined in section $408(b)(2)(B)(ii)(dd)(AA)$
7	of the Employee Retirement Income Security
8	Act of 1974) to brokers, consultants, advisors,
9	or any other individual or firm who referred the
10	group health plan's business to the pharmacy
11	benefit manager; and
12	"(H) a summary document that includes
13	such information described in subparagraphs
14	(A) through (G) as the Secretary determines
15	useful for plan sponsors for purposes of select-
16	ing pharmacy benefit management services,
17	such as an estimated net price to plan sponsor
18	and participant or beneficiary, a cost per claim,
19	the fee structure or reimbursement model, and
20	estimated cost per participant or beneficiary.
21	"(2) Supplementary reporting for intra-
22	COMPANY PRESCRIPTION DRUG TRANSACTIONS.—
23	"(A) In General.—A health insurance
24	issuer offering covered group health insurance
25	coverage or an entity providing pharmacy ben-

efit management services under a covered group health plan or covered group health insurance coverage shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

"(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that issuer or entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and copayment incentives funded by an entity providing pharmacy benefit management services;

"(ii) the percentage of total prescriptions charged to the plan, coverage, or participants and beneficiaries in the plan or coverage, that were dispensed by mail order, specialty, or retail pharmacies that are wholly or partially-owned by the issuer

1	or entity providing pharmacy benefit man-
2	agement services; and
3	"(iii) a list of all drugs dispensed by
4	such wholly or partially-owned pharmacy
5	and charged to the plan or coverage, or
6	participants and beneficiaries of the plan
7	or coverage, during the applicable quarter,
8	and, with respect to each drug—
9	"(I) the amounts charged, per
10	dosage unit, per course of treatment,
11	per 30-day supply, and per 90-day
12	supply, with respect to participants
13	and beneficiaries in the plan or cov-
14	erage, including amounts charged to
15	the plan or coverage and amounts
16	charged to the participants and bene-
17	ficiaries;
18	"(II) the median amount charged
19	to the plan or coverage, per dosage
20	unit, per course of treatment, per 30-
21	day supply, and per 90-day supply, in-
22	cluding amounts paid by the partici-
23	pants and beneficiaries, when the
24	same drug is dispensed by other phar-
25	macies that are not wholly or par-

1	tially-owned by the issuer or entity
2	and that are included in the pharmacy
3	network of that plan or coverage;
4	"(III) the interquartile range of
5	the costs, per dosage unit, per course
6	of treatment, per 30-day supply, and
7	per 90-day supply, including amounts
8	paid by the participants and bene-
9	ficiaries, when the same drug is dis-
10	pensed by other pharmacies that are
11	not wholly or partially-owned by the
12	issuer or entity and that are included
13	in the pharmacy network of that plan
14	or coverage;
15	"(IV) the lowest cost, per dosage
16	unit, per course of treatment, per 30-
17	day supply, and per 90-day supply,
18	for such drug, including amounts
19	charged to the plan or issuer and par-
20	ticipants and beneficiaries, that is
21	available from any pharmacy included
22	in the network of the plan or cov-
23	erage;
24	"(V) the net acquisition cost per
25	dosage unit and for a 30 day-supply,

and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and

"(VI) other information with respect to the cost of the drug, as determined by the Secretary, such as average sales price, wholesale acquisition cost, and national average drug acquisition cost per dosage unit, per typical course of treatment, or per 30-day supply, for such drug, including amounts charged to the plan or issuer and participants and beneficiaries among all pharmacies included in the network of the plan or coverage.

"(B) Plans and coverage offered by SMALL EMPLOYERS.—A health insurance issuer offering covered group health insurance coverage that is not covered group health insurance coverage or an entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan or under group health insurance coverage that is not covered group health insurance coverage

erage that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

## "(3) Privacy requirements.—

"(A) Relationship to hipaa regulations.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the privacy, security, breach notification, and enforcement regulations in parts 160 and 164 of title 45, Code of Federal Regulations (or successor regulations).

"(B) REQUIREMENT.—A report submitted under paragraph (1) or (2) shall contain only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

"(C) CLARIFICATION REGARDING CERTAIN
DISCLOSURES OF INFORMATION.—

Nothing in this section prevents a health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage from placing reasonable restrictions on the public disclosure of the information contained in a report under paragraph (1) or (2).

"(ii) LIMITATIONS.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan or group health insurance coverage may not restrict disclosure of such reports to the Department of Health and Human Services, the Department of Labor, the Department of the Treasury, or any other Federal agency responsible for enforcement activities under this section for purposes of enforcement under this section or other applicable law, or to the Comptroller General of the

1	United States in accordance with para-
2	graph (6).
3	"(4) Use and disclosure by plan spon-
4	SORS.—
5	"(A) Prohibition.—A plan sponsor may
6	not—
7	"(i) fail or refuse to hire, or dis-
8	charge, any employee, or otherwise dis-
9	criminate against any employee with re-
10	spect to the compensation, terms, condi-
11	tions, or privileges of employment of the
12	employee, because of information sub-
13	mitted under paragraph (1) or (2) attrib-
14	uted to the employee or a dependent of the
15	employee; or
16	"(ii) limit, segregate, or classify the
17	employees of the employer in any way that
18	would deprive or tend to deprive any em-
19	ployee of employment opportunities or oth-
20	erwise adversely affect the status of the
21	employee as an employee, because of infor-
22	mation submitted under paragraph (1) or
23	(2) attributed to the employee or a depend-
24	ent of the employee.

1	"(B) DISCLOSURE AND REDISCLOSURE.—
2	A plan sponsor shall not disclose the informa-
3	tion received under paragraph (1) or (2) ex-
4	cept—
5	"(i) to an occupational or other health
6	researcher if the research is conducted in
7	compliance with the regulations and pro-
8	tections provided for under part 46 of title
9	45, Code of Federal Regulations (or suc-
10	cessor regulations);
11	"(ii) in response to an order of a
12	court, except that the plan sponsor may
13	disclose only the information expressly au-
14	thorized by such order;
15	"(iii) to the Department of Health
16	and Human Services, the Department of
17	Labor, the Department of the Treasury, or
18	other Federal agency responsible for en-
19	forcement activities under this section; or
20	"(iv) to a contractor or agent for pur-
21	poses of health plan administration, if such
22	contractor or agent agrees, in writing, to
23	abide by the same use and disclosure re-
24	strictions as the plan sponsor.

"(C) Relationship to hipaa regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act and section 264 of the Health Insurance Portability and Accountability Act of 1996, subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

#### "(D) Enforcement.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Non-discrimination Act to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) Prohibition against retaliation.—No person shall discriminate against any individual because such indi-

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vidual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

#### "(5) Additional reporting.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL EMPLOYERS.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury may deter-

1	mine. Each such report shall include, with re-
2	spect to the applicable group health plan, the
3	information described in subparagraphs (A),
4	(D), (E), (F), (G), and (H) of paragraph (1).
5	"(B) Opt-in for group health insur-
6	ANCE COVERAGE.—
7	"(i) In general.—A plan sponsor
8	may, on an annual basis, beginning with
9	plan years beginning on or after January
10	1, 2025, elect to require a health insurance
11	issuer offering group health insurance cov-
12	erage to submit to such plan sponsor a re-
13	port in accordance with this subsection.
14	"(ii) Contents of Reports.—
15	"(I) COVERED GROUP HEALTH
16	INSURANCE COVERAGE.—In the case
17	of an issuer that offers covered group
18	health insurance coverage, a report
19	provided pursuant to clause (i) shall
20	include, with respect to the applicable
21	covered group health insurance cov-
22	erage, the information required under
23	paragraph (1) for covered group
24	health plans.

1	"(II) OTHER GROUP HEALTH IN-
2	SURANCE COVERAGE.—In the case of
3	an issuer that offers group health in-
4	surance coverage that is not covered
5	group health insurance, a report pro-
6	vided pursuant to clause (i) shall in-
7	clude, with respect to the applicable
8	group health insurance coverage, the
9	information described in subpara-
10	graphs (A), (D), (E), (F), and (G) of
11	paragraph (1).
12	"(iii) Application.—For purposes of
13	reports submitted in accordance with this
14	subparagraph, paragraph (1) shall be ap-
15	plied by substituting 'group health insur-
16	ance coverage' or 'health insurance issuer',
17	as applicable, for 'group health plan',
18	'group plan', and 'plan' where such terms
19	appear in such paragraph.
20	"(iv) Required reporting for all
21	GROUP HEALTH INSURANCE COVERAGE.—
22	Each health insurance issuer of health in-
23	surance coverage shall annually submit the
24	information described in paragraph (1)(H),
25	regardless of whether the plan sponsor

1 made the election described in clause (i) 2 for the applicable year.

"(6) Submissions to Gao.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (3), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

#### "(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Labor, and the Sec-

retary of the Treasury shall define through rulemaking a limited form of the reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

# "(c) Limitations on Spread Pricing.—

"(1) In General.—For plan years beginning on or after January 1, 2025, a group health plan or health insurance issuer offering group or individual health insurance coverage shall not charge participants and beneficiaries, and an entity providing pharmacy benefit management services under such a plan or coverage shall not charge the plan, issuer, or participants and beneficiaries, a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.

"(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:

1	"(A) A penalty paid if an original claim for
2	a prescription drug was submitted fraudulently
3	by the pharmacy to the plan, issuer, or entity
4	"(B) A penalty paid if the original claim
5	payment made by the plan, issuer, or entity to
6	the pharmacy was inconsistent with the reim-
7	bursement terms in any contract between the
8	pharmacy and the plan, issuer, or entity.
9	"(C) A penalty paid if the pharmacist serv-
10	ices billed to the plan, issuer, or entity were not
11	rendered by the pharmacy.
12	"(d) Full Rebate Pass-Through to Plan.—
13	"(1) In general.—For plan years beginning
14	on or after January 1, 2025, a third-party adminis-
15	trator of a group health plan, a health insurance
16	issuer offering group health insurance coverage, or
17	an entity providing pharmacy benefit management
18	services under such health plan or health insurance
19	coverage shall—
20	"(A) remit 100 percent of rebates, fees, al-
21	ternative discounts, and other remuneration re-
22	ceived from any applicable entity that are re-
23	lated to utilization of drugs under such health
24	plan or health insurance coverage, to the group
25	health plan; and

1	"(B) ensure that any contract entered into
2	by such third-party administrator, health insur-
3	ance issuer, or entity providing pharmacy ben-
4	efit management services with an applicable en-
5	tity remit 100 percent of rebates, fees, alter-
6	native discounts, and other remuneration re-
7	ceived to the third-party administrator, health
8	insurance issuer, or entity providing pharmacy
9	benefit management services.
10	"(2) Form and manner of remittance.—
11	Such rebates, fees, alternative discounts, and other
12	remuneration shall be—
13	"(A) remitted to the group health plan or
14	group health insurance coverage in a timely
15	fashion after the period for which such rebates,
16	fees, alternative discounts, or other remunera-
17	tion is calculated, and in no case later than 90
18	days after the end of such period;
19	"(B) fully disclosed and enumerated to the
20	group health plan sponsor, as described in para-
21	graphs (1) and (4) of subsection (b);
22	"(C) available for audit by the plan spon-
23	sor, or a third-party designated by a plan spon-
24	sor not less than once per plan year; and

- "(D) returned to the issuer or entity providing pharmaceutical benefit management services by the group health plan if audits by such issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan.
  - "(3) Audit of Rebate Contracts.—A thirdparty administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by such plan sponsor or designated thirdparty, subject to confidentiality agreements to prevent re-disclosure of such contracts.
    - "(4) AUDITORS.—The applicable plan sponsor may select an auditor for purposes of carrying out audits under paragraphs (2)(C) and (3).
    - "(5) Rule of construction.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not contemplated by this subsection, pro-

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vided that such fees are transparent to group health plans and health insurance issuers.

### "(e) Enforcement.—

- "(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall enforce this section.
- "(2) Failure to provide timely information.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services that violates subsection (d) shall be subject to a civil monetary penalty in the amount of \$10,000 for each day during which such violation continues or such information is not disclosed or reported.
- "(3) False information.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be

- subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.
- 5 "(4) Procedure.—The provisions of section 6 1128A of the Social Security Act, other than sub-7 sections (a) and (b) and the first sentence of sub-8 section (c)(1) of such section shall apply to civil 9 monetary penalties under this subsection in the 10 same manner as such provisions apply to a penalty 11 or proceeding under section 1128A of the Social Se-12 curity Act.
  - "(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.
- "(f) Rule of Construction.—Nothing in this section shall be construed to permit a health insurance issuer, group health plan, or other entity to restrict disclosure to, or otherwise limit the access of, the Department of Health and Human Services to a report described in subsection (b)(1) or information related to compliance with sub-

section (a) by such issuer, plan, or entity.

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1	"(g) Definitions.—In this section—
2	"(1) the term 'applicable entity' means—
3	"(A) a drug manufacturer, distributor,
4	wholesaler, rebate aggregator (or other pur-
5	chasing entity designed to aggregate rebates),
6	group purchasing organization, or associated
7	third party;
8	"(B) any subsidiary, parent, affiliate, or
9	subcontractor of a group health plan, health in-
10	surance issuer, entity that provides pharmacy
11	benefit management services on behalf of such
12	a plan or issuer, or any entity described in sub-
13	paragraph (A); or
14	"(C) such other entity as the Secretary,
15	the Secretary of Labor, and the Secretary of
16	the Treasury may specify through rulemaking;
17	"(2) the term 'covered group health insurance
18	coverage' means health insurance coverage offered in
19	connection with a group health plan maintained by
20	a large employer;
21	"(3) the term 'covered group health plan'
22	means a group health plan maintained by a large
23	employer;
24	"(4) the term 'gross spending', with respect to
25	prescription drug benefits under a group health plan

- or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of manufacturer rebates, fees, alternative discounts, or other remuneration;
  - "(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;
  - "(6) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;
  - "(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974;
  - "(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of

1	Labor, and the Secretary of the Treasury, through
2	notice and comment rulemaking;
3	"(9) the term 'small employer' means, in con-
4	nection with a group health plan with respect to a
5	calendar year and a plan year, an employer who em-
6	ployed an average of at least 1 but not more than
7	49 employees on business days during the preceding
8	calendar year and who employs at least 1 employee
9	on the first day of the plan year; and
10	"(10) the term 'wholesale acquisition cost' has
11	the meaning given such term in section
12	1847A(c)(6)(B) of the Social Security Act."; and
13	(2) in section 2723 (42 U.S.C. 300gg–22)—
14	(A) in subsection (a)—
15	(i) in paragraph (1), by inserting
16	"(other than section 2799A–11)" after
17	"part D"; and
18	(ii) in paragraph (2), by inserting
19	"(other than section 2799A-11)" after
20	"part D";
21	(B) in subsection (b)—
22	(i) in paragraph (1), by inserting
23	"(other than section 2799A-11)" after
24	"part D";

1	(ii) in paragraph (2)(A), by inserting
2	"(other than section 2799A–11)" after
3	"part D"; and
4	(iii) in paragraph (2)(C)(ii), by insert-
5	ing "(other than section 2799A–11)" after
6	"part D".
7	(b) ERISA.—
8	(1) IN GENERAL.—Subtitle B of title I of the
9	Employee Retirement Income Security Act of 1974
10	(29 U.S.C. 1021 et seq.) is amended—
11	(A) in subpart B of part 7 (29 U.S.C.
12	1185 et seq.), by adding at the end the fol-
	lowing:
13	lowing: "SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-
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13 14 15 16	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-
13 14 15	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR- MACY BENEFIT MANAGEMENT SERVICES.
13 14 15 16 17	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or
13 14 15 16 17	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage
13 14 15 16 17 18	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage
13 14 15 16 17 18	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) In General.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity providing
13 14 15 16 17 18 19 20	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity providing pharmacy benefit management services on behalf of such
13 14 15 16 17 18 19 20 21	"SEC. 726. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-MACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan (or health insurance issuer offering group health insurance coverage in connection with such a plan) or an entity providing pharmacy benefit management services on behalf of such a plan or issuer shall not enter into a contract with an

ment services on behalf of a plan or issuer, from making 2 the reports described in subsection (b). 3 "(b) Reports.— "(1) In General.—For plan years beginning 4 5 on or after January 1, 2025, not less frequently 6 than annually, an entity providing pharmacy benefit 7 management services on behalf of a covered group 8 health plan shall submit to the plan sponsor of such 9 covered group health plan a report in accordance 10 with this subsection and make such report available 11 to the plan sponsor in a machine-readable format 12 and, as the Secretary may determine, other formats. 13 Each such report shall include, with respect to the 14 covered group health plan— "(A) as applicable, information collected 15 16 from drug manufacturers by such issuer or en-17 tity on the total amount of copayment assist-18 ance dollars paid, or copayment cards applied, 19 that were funded by the drug manufacturer 20 with respect to the participants and bene-21 ficiaries in such plan; 22 "(B) a list of each drug covered by such 23 plan or entity providing pharmacy benefit man-

agement services that was billed during the re-

1	porting period, including, with respect to each
2	such drug during the reporting period—
3	"(i) the brand name, generic or non-
4	proprietary name, and National Drug
5	Code;
6	"(ii) the number of participants and
7	beneficiaries for whom the drug was billed
8	during the reporting period, the total num-
9	ber of prescription claims for the drug (in-
10	cluding original prescriptions and refills),
11	and the total number of dosage units of
12	the drug dispensed across the reporting pe-
13	riod;
14	"(iii) for each claim or dosage unit de-
15	scribed in clause (ii), the type of dis-
16	pensing channel used, such as retail, mail
17	order, or specialty pharmacy;
18	"(iv) the wholesale acquisition cost,
19	listed as cost per days supply, cost per dos-
20	age unit, and cost per typical course of
21	treatment (as applicable);
22	"(v) the total out-of-pocket spending
23	by participants and beneficiaries on such
24	drug after application of any benefits
25	under the plan or coverage, including par-

1	ticipant and beneficiary spending through
2	copayments, coinsurance, and deductibles,
3	but not including any amounts spent by
4	participants and beneficiaries on drugs not
5	covered under the plan or coverage or for
6	which no claim is submitted to the plan or
7	coverage; and
8	"(vi) for any drug for which gross
9	spending by the plan exceeded \$10,000
10	and that is one of the 50 prescription
11	drugs for which the group health plan
12	spent the most on prescription drug bene-
13	fits during the reporting period—
14	"(I) a list of all other drugs in
15	the same therapeutic class, including
16	brand name drugs and biological
17	products and generic drugs or bio-
18	similar biological products that are in
19	the same therapeutic class as such
20	drug; and
21	"(II) if applicable, the rationale
22	for preferred formulary placement of
23	such drug in that therapeutic class,
24	selected from a list of standard ra-
25	tionales established by the Secretary:

1	"(C) a list of each therapeutic class of
2	drugs that were dispensed under the health
3	plan during the reporting period, and, with re-
4	spect to each such therapeutic class of drugs,
5	during the reporting period—
6	"(i) total gross spending by the plan,
7	before rebates, fees, alternative discounts,
8	or other remuneration;
9	"(ii) the number of participants and
10	beneficiaries who filled a prescription for a
11	drug in that class;
12	"(iii) if applicable to that class, a de-
13	scription of the formulary tiers and utiliza-
14	tion management mechanisms (such as
15	prior authorization or step therapy) em-
16	ployed for drugs in that class;
17	"(iv) the total out-of-pocket spending
18	by participants and beneficiaries, including
19	participant and beneficiary spending
20	through copayments, coinsurance, and
21	deductibles; and
22	"(v) for each therapeutic class under
23	which 3 or more drugs are included on the
24	formulary of such plan—

1	"(I) the amount received, or ex-
2	pected to be received, by such entity,
3	from an applicable entity, in rebates,
4	fees, alternative discounts, or other
5	remuneration that—
6	"(aa) has been paid, or will
7	be paid, by such an applicable
8	entity for claims incurred during
9	the reporting period; or
10	"(bb) is related to utilization
11	of drugs or drug spending;
12	"(II) the total net spending by
13	the health plan on that class of drugs;
14	and
15	"(III) the net price per typical
16	course of treatment or 30-day supply
17	incurred by the health plan and its
18	participants and beneficiaries, after
19	rebates, fees, alternative discounts, or
20	other remuneration provided by an
21	applicable entity, for drugs dispensed
22	within such therapeutic class during
23	the reporting period;
24	"(D) total gross spending on prescription
25	drugs by the plan during the reporting period,

1 before rebates, fees, alternative discounts, or 2 other remuneration provided by an applicable 3 entity; "(E) the total amount received, or ex-4 5 pected to be received, by the health plan, from 6 an applicable entity, in rebates, fees, alternative 7 discounts, and other remuneration received 8 from any such entities, related to utilization of 9 drug or drug spending under that health plan 10 during the reporting period; 11 "(F) the total net spending on prescription 12 drugs by the health plan during the reporting 13 period; 14 "(G) amounts paid directly or indirectly in 15 rebates, fees, or any other type of compensation (as defined in section 408(b)(2)(B)(ii)(dd)(AA)) 16 to brokers, consultants, advisors, or any other 17 18 individual or firm who referred the group health 19 plan's business to the pharmacy benefit man-20 ager; and "(H) a summary document that includes 21 22 such information described in subparagraphs 23 (A) through (G) as the Secretary determines

useful for plan sponsors for purposes of select-

ing pharmacy benefit management services,

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1	such as an estimated net price to plan sponsor
2	and participant or beneficiary, a cost per claim,
3	the fee structure or reimbursement model, and
4	estimated cost per participant or beneficiary.
5	"(2) Supplementary reporting for intra-
6	COMPANY PRESCRIPTION DRUG TRANSACTIONS.—
7	"(A) In General.—A health insurance
8	issuer offering covered group health insurance
9	coverage or an entity providing pharmacy ben-
10	efit management services under a covered group
11	health plan or covered group health insurance
12	coverage shall submit, together with the report
13	under paragraph (1), a supplementary report
14	every 6 months to the plan sponsor that in-
15	cludes—
16	"(i) an explanation of any benefit de-
17	sign parameters that encourage or require
18	participants and beneficiaries in the plan
19	or coverage to fill prescriptions at mail
20	order, specialty, or retail pharmacies that

erage, including mandatory mail and specialty home delivery programs, retail and

are wholly or partially-owned by that issuer

or entity providing pharmacy benefit man-

agement services under such plan or cov-

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1	mail auto-refill programs, and copayment
2	incentives funded by an entity providing
3	pharmacy benefit management services;
4	"(ii) the percentage of total prescrip-
5	tions charged to the plan, coverage, or par-
6	ticipants and beneficiaries in the plan or
7	coverage, that were dispensed by mail
8	order, specialty, or retail pharmacies that
9	are wholly or partially-owned by the issuer
10	or entity providing pharmacy benefit man-
11	agement services; and
12	"(iii) a list of all drugs dispensed by
13	such wholly or partially-owned pharmacy
14	and charged to the plan or coverage, or
15	participants and beneficiaries of the plan
16	or coverage, during the applicable quarter,
17	and, with respect to each drug—
18	"(I) the amounts charged, per
19	dosage unit, per course of treatment,
20	per 30-day supply, and per 90-day
21	supply, with respect to participants
22	and beneficiaries in the plan or cov-
23	erage, including amounts charged to
24	the plan or coverage and amounts

1	charged to the participants and bene-
2	ficiaries;
3	"(II) the median amount charged
4	to the plan or coverage, per dosage
5	unit, per course of treatment, per 30-
6	day supply, and per 90-day supply, in-
7	cluding amounts paid by the partici-
8	pants and beneficiaries, when the
9	same drug is dispensed by other phar-
10	macies that are not wholly or par-
11	tially-owned by the issuer or entity
12	and that are included in the pharmacy
13	network of that plan or coverage;
14	"(III) the interquartile range of
15	the costs, per dosage unit, per course
16	of treatment, per 30-day supply, and
17	per 90-day supply, including amounts
18	paid by the participants and bene-
19	ficiaries, when the same drug is dis-
20	pensed by other pharmacies that are
21	not wholly or partially-owned by the
22	issuer or entity and that are included
23	in the pharmacy network of that plan
24	or coverage;

1	"(IV) the lowest cost, per dosage
2	unit, per course of treatment, per 30-
3	day supply, and per 90-day supply,
4	for such drug, including amounts
5	charged to the plan or issuer and par-
6	ticipants and beneficiaries, that is
7	available from any pharmacy included
8	in the network of the plan or cov-
9	erage;
10	"(V) the net acquisition cost per
11	dosage unit and for a 30 day-supply,
12	and the acquisition cost per typical
13	course of treatment, if the drug is
14	subject to a maximum price discount;
15	and
16	"(VI) other information with re-
17	spect to the cost of the drug, as deter-
18	mined by the Secretary, such as aver-
19	age sales price, wholesale acquisition
20	cost, and national average drug acqui-
21	sition cost per dosage unit, per typical
22	course of treatment, or per 30-day
23	supply, for such drug, including
24	amounts charged to the plan or issuer

and participants and beneficiaries

1 among all pharmacies included in the 2 network of the plan or coverage.

> "(B) Plans and Coverage offered by SMALL EMPLOYERS.—A health insurance issuer offering covered group health insurance coverage that is not covered group health insurance coverage or an entity providing pharmacy benefit management services under a group health plan that is not a covered group health plan or under group health insurance coverage that is not covered group health insurance coverage that conducts transactions with a wholly or partially-owned pharmacy shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes the information described in clauses (i) and (ii) of subparagraph (A).

### "(3) Privacy requirements.—

"(A) Relationship to hipaa regulations.—Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the privacy, security, breach notification, and enforcement

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1	regulations in parts 160 and 164 of title 45,
2	Code of Federal Regulations (or successor regu-
3	lations).
4	"(B) REQUIREMENT.—A report submitted
5	under paragraph (1) or (2) shall contain only
6	summary health information, as defined in sec-
7	tion 164.504(a) of title 45, Code of Federal
8	Regulations (or successor regulations).
9	"(C) Clarification regarding certain
10	DISCLOSURES OF INFORMATION.—
11	"(i) Reasonable restrictions.—
12	Nothing in this section prevents a health
13	insurance issuer offering group health in-
14	surance coverage or an entity providing
15	pharmacy benefit management services on
16	behalf of a group health plan or group
17	health insurance coverage from placing
18	reasonable restrictions on the public disclo-
19	sure of the information contained in a re-
20	port under paragraph (1) or (2).
21	"(ii) Limitations.—A health insur-
22	ance issuer offering group health insurance
23	coverage or an entity providing pharmacy
24	benefit management services on behalf of a

group health plan or group health insur-

1	ance coverage may not restrict disclosure
2	of such reports to the Department of
3	Health and Human Services, the Depart-
4	ment of Labor, the Department of the
5	Treasury, or any other Federal agency re-
6	sponsible for enforcement activities under
7	this section for purposes of enforcement
8	under this section or other applicable law,
9	or to the Comptroller General of the
10	United States in accordance with para-
11	graph (6).
12	"(4) USE AND DISCLOSURE BY PLAN SPON-
13	SORS.—
14	"(A) Prohibition.—A plan sponsor may
15	not—
16	"(i) fail or refuse to hire, or dis-
17	charge, any employee, or otherwise dis-
18	criminate against any employee with re-
19	spect to the compensation, terms, condi-
20	tions, or privileges of employment of the
21	employee, because of information sub-
22	mitted under paragraph (1) or (2) attrib-
23	uted to the employee or a dependent of the

1	"(ii) limit, segregate, or classify the
2	employees of the employer in any way that
3	would deprive or tend to deprive any em-
4	ployee of employment opportunities or oth-
5	erwise adversely affect the status of the
6	employee as an employee, because of infor-
7	mation submitted under paragraph (1) or
8	(2) attributed to the employee or a depend-
9	ent of the employee.
10	"(B) DISCLOSURE AND REDISCLOSURE.—
11	A plan sponsor shall not disclose the informa-
12	tion received under paragraph (1) or (2) ex-
13	$\operatorname{cept}$ —
14	"(i) to an occupational or other health
15	researcher if the research is conducted in
16	compliance with the regulations and pro-
17	tections provided for under part 46 of title
18	45, Code of Federal Regulations (or suc-
19	cessor regulations);
20	"(ii) in response to an order of a
21	court, except that the plan sponsor may
22	disclose only the information expressly au-
23	thorized by such order;
24	"(iii) to the Department of Health
25	and Human Services, the Department of

Labor, the Department of the Treasury, or other Federal agency responsible for enforcement activities under this section; or

> "(iv) to a contractor or agent for purposes of health plan administration, if such contractor or agent agrees, in writing, to abide by the same use and disclosure restrictions as the plan sponsor.

"(C) Relationship to hipaa regulations.—With respect to the regulations promulgated by the Secretary of Health and Human Services under part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2), subparagraph (B) does not prohibit a covered entity (as defined for purposes of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

"(D) Enforcement.—

"(i) IN GENERAL.—The powers, pro-1 2 cedures, and remedies provided in section 207 of the Genetic Information Non-3 discrimination Act (42 U.S.C. 2000ff-6) to a person alleging a violation of title II of 6 such Act shall be the powers, procedures, 7 and remedies this subparagraph provides 8 for any person alleging a violation of this 9 paragraph. 10 "(ii) Prohibition against retalia-11 TION.—No person shall

"(ii) Prohibition against retaliation.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The remedies and procedures otherwise provided for under this subparagraph shall be available to aggrieved individuals with respect to violations of this clause.

### "(5) Additional reporting.—

"(A) REPORTING WITH RESPECT TO GROUP HEALTH PLANS OFFERED BY SMALL

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EMPLOYERS.—For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format, and such other formats as the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor may determine. Each such report shall include, with respect to the applicable group health plan, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

# "(B) OPT-IN FOR GROUP HEALTH INSUR-ANCE COVERAGE.—

"(i) IN GENERAL.—A plan sponsor may, on an annual basis, beginning with plan years beginning on or after January 1, 2025, elect to require a health insurance issuer offering group health insurance coverage to submit to such plan sponsor a report in accordance with this subsection.

1	"(ii) Contents of Reports.—
2	"(I) Covered group health
3	INSURANCE COVERAGE.—In the case
4	of an issuer that offers covered group
5	health insurance coverage, a report
6	provided pursuant to clause (i) shall
7	include, with respect to the applicable
8	covered group health insurance cov-
9	erage, the information required under
10	paragraph (1) for covered group
11	health plans.
12	"(II) OTHER GROUP HEALTH IN-
13	SURANCE COVERAGE.—In the case of
14	an issuer that offers group health in-
15	surance coverage that is not covered
16	group health insurance, a report pro-
17	vided pursuant to clause (i) shall in-
18	clude, with respect to the applicable
19	group health insurance coverage, the
20	information described in subpara-
21	graphs (A), (D), (E), (F), and (G) of
22	paragraph (1).
23	"(iii) Application.—For purposes of
24	reports submitted in accordance with this
25	subparagraph, paragraph (1) shall be ap-

plied by substituting 'group health insurance coverage' or 'health insurance issuer', as applicable, for 'group health plan', 'group plan', and 'plan' where such terms appear in such paragraph.

"(iv) REQUIRED REPORTING FOR ALL GROUP HEALTH INSURANCE COVERAGE.— Each health insurance issuer of health insurance coverage shall annually submit the information described in paragraph (1)(H), regardless of whether the plan sponsor made the election described in clause (i) for the applicable year.

"(6) Submissions to Gao.—A health insurance issuer offering group health insurance coverage or an entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such coverage or plan, and other such reports as requested, in accordance with the privacy requirements under paragraph (3), and such other information that the Comptroller General determines

necessary to carry out the study under section 2(f)
 of the Pharmacy Benefit Manager Reform Act.

## "(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) Limited form of report.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall define through rulemaking a limited form of the reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anticompetitive behavior.

# "(c) Limitations on Spread Pricing.—

"(1) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or

- health insurance issuer offering group health insurance coverage shall not charge participants and beneficiaries, and an entity providing pharmacy benefit management services under such a plan or coverage shall not charge the plan, issuer, or participants and beneficiaries, a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties paid by the pharmacy (as described in paragraph (2)) to such plan, issuer, or entity.
  - "(2) RULE OF CONSTRUCTION.—For purposes of paragraph (1), penalties paid by pharmacies include only the following:
    - "(A) A penalty paid if an original claim for a prescription drug was submitted fraudulently by the pharmacy to the plan, issuer, or entity.
    - "(B) A penalty paid if the original claim payment made by the plan, issuer, or entity to the pharmacy was inconsistent with the reimbursement terms in any contract between the pharmacy and the plan, issuer, or entity.
    - "(C) A penalty paid if the pharmacist services billed to the plan, issuer, or entity were not rendered by the pharmacy.
- 25 "(d) Full Rebate Pass-Through to Plan.—

"(1) In General.—For plan years beginning on or after January 1, 2025, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services under such health plan or health insurance coverage shall—

"(A) remit 100 percent of rebates, fees, alternative discounts, and other applicable remuneration received from any applicable entity that are related to utilization of drugs under such health plan or health insurance coverage, to the group health plan; and

"(B) ensure that any contract entered into by such third-party administrator, health insurance issuer, or entity providing pharmacy benefit management services with an applicable entity remit 100 percent of rebates, fees, alternative discounts, and other remuneration received to the third-party administrator, health insurance issuer, or entity providing pharmacy benefit management services.

"(2) FORM AND MANNER OF REMITTANCE.— Such rebates, fees, alternative discounts, and other remuneration shall be—

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1	"(A) remitted to the group health plan or
2	group health insurance coverage in a timely
3	fashion after the period for which such rebates,
4	fees, alternative discounts, or other remunera-
5	tion is calculated, and in no case later than 90
6	days after the end of such period;
7	"(B) fully disclosed and enumerated to the
8	group health plan sponsor, as described in para-
9	graphs (1) and (4) of subsection (b);
10	"(C) available for audit by the plan spon-
11	sor, or a third-party designated by a plan spon-
12	sor not less than once per plan year; and
13	"(D) returned to the issuer or entity pro-
14	viding pharmaceutical benefit management
15	services by the group health plan if audits by
16	such issuer or entity indicate that the amounts
17	received are incorrect after such amounts have
18	been paid to the group health plan.
19	"(3) Audit of Rebate Contracts.—A third-
20	party administrator of a group health plan, a health
21	insurance issuer offering group health insurance cov-
22	erage, or an entity providing pharmacy benefit man-
23	agement services under such health plan or health
24	insurance coverage shall make rebate contracts with

rebate aggregators or drug manufacturers available

- for audit by such plan sponsor or designated thirdparty, subject to confidentiality agreements to prevent re-disclosure of such contracts.
  - "(4) AUDITORS.—The applicable plan sponsor may select an auditor for purposes of carrying out audits under paragraphs (2)(C) and (3).
  - "(5) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit payments to entities offering pharmacy benefit management services for bona fide services using a fee structure not contemplated by this subsection, provided that such fees are transparent to group health plans and health insurance issuers.

### "(e) Enforcement.—

- "(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Health and Human Services and the Secretary of the Treasury, shall enforce this section.
- "(2) Failure to provide timely information.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan, health insurance issuer, or entity providing pharmacy benefit management services that violates sub-

section (c); or a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services that violates subsection (d) shall be subject to a civil monetary penalty in the amount of \$10,000 for each day dur-ing which such violation continues or such informa-tion is not disclosed or reported.

"(3) False information.—A health insurance issuer, entity providing pharmacy benefit management services, or drug manufacturer that knowingly provides false information under this section shall be subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalty shall be in addition to other penalties as may be prescribed by law.

"(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.

1	"(5) Waivers.—The Secretary may waive pen-
2	alties under paragraph (2), or extend the period of
3	time for compliance with a requirement of this sec-
4	tion, for an entity in violation of this section that
5	has made a good-faith effort to comply with this sec-
6	tion.
7	"(f) Rule of Construction.—Nothing in this sec-
8	tion shall be construed to permit a health insurance issuer,
9	group health plan, or other entity to restrict disclosure to,
10	or otherwise limit the access of, the Department of Labor
11	to a report described in subsection (b)(1) or information
12	related to compliance with subsection (a) by such issuer,
13	plan, or entity.
14	"(g) Definitions.—In this section—
15	"(1) the term 'applicable entity' means—
16	"(A) a drug manufacturer, distributor,
17	wholesaler, rebate aggregator (or other pur-
18	chasing entity designed to aggregate rebates),
19	group purchasing organization, or associated
20	third party;
21	"(B) any subsidiary, parent, affiliate, or
22	subcontractor of a group health plan, health in-
23	surance issuer, entity that provides pharmacy
24	benefit management services on behalf of such

1	a plan or issuer, or any entity described in sub-
2	paragraph (A); or
3	"(C) such other entity as the Secretary,
4	the Secretary of Health and Human Services,
5	and the Secretary of the Treasury may specify
6	through rulemaking;
7	"(2) the term 'covered group health insurance
8	coverage' means health insurance coverage offered in
9	connection with a group health plan maintained by
10	a large employer;
11	"(3) the term 'covered group health plan'
12	means a group health plan maintained by a large
13	employer;
14	"(4) the term 'gross spending', with respect to
15	prescription drug benefits under a group health plan
16	or health insurance coverage, means the amount
17	spent by a group health plan or health insurance
18	issuer on prescription drug benefits, calculated be-
19	fore the application of manufacturer rebates, fees,
20	alternative discounts, or other remuneration;
21	"(5) the term 'large employer' means, in con-
22	nection with a group health plan with respect to a
23	calendar year and a plan year, an employer who em-
24	ployed an average of at least 50 employees on busi-

ness days during the preceding calendar year and

- who employs at least 1 employee on the first day of the plan year;
- "(6) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;
  - "(7) the term 'plan sponsor' has the meaning given such term in section 3(16)(B);
  - "(8) the term 'remuneration' has the meaning given such term by the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, through notice and comment rulemaking;
  - "(9) the term 'small employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 49 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year; and
- 24 "(10) the term 'wholesale acquisition cost' has 25 the meaning given such term in section

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1	1847A(c)(6)(B) of the Social Security Act (42
2	U.S.C. $1395w-3a(e)(6)(B)$ )."; and
3	(B) in section 502(b)(3) (29 U.S.C.
4	1132(b)(3)), by inserting "(other than section
5	726)" after "part 7".
6	(2) CLERICAL AMENDMENT.—The table of con-
7	tents in section 1 of the Employee Retirement In-
8	come Security Act of 1974 (29 U.S.C. 1001 et seq.)
9	is amended by inserting after the item relating to
10	section 725 the following new item:
	"Sec. 726. Oversight of entities that provide pharmacy benefit management services.".
11	(c) Internal Revenue Code.—
12	(1) In General.—Subchapter B of chapter
12 13	(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amend-
13	100 of the Internal Revenue Code of 1986 is amend-
13 14	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:
13 14 15	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHAR-
13 14 15 16	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.
13 14 15 16 17	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or
13 14 15 16 17	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity
13 14 15 16 17 18	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity providing pharmacy benefit management services on be-
13 14 15 16 17 18 19 20	100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:  "SEC. 9826. OVERSIGHT OF ENTITIES THAT PROVIDE PHARMACY BENEFIT MANAGEMENT SERVICES.  "(a) IN GENERAL.—For plan years beginning on or after January 1, 2025, a group health plan or an entity providing pharmacy benefit management services on behalf of such a plan shall not enter into a contract with

1 services on behalf of a plan, from making the reports de-2 scribed in subsection (b). 3 "(b) Reports.— "(1) In General.—For plan years beginning 4 5 on or after January 1, 2025, not less frequently 6 than annually, an entity providing pharmacy benefit 7 management services on behalf of a covered group 8 health plan shall submit to the plan sponsor of such 9 covered group health plan a report in accordance 10 with this subsection and make such report available 11 to the plan sponsor in a machine-readable format 12 and, as the Secretary may determine, other formats. 13 Each such report shall include, with respect to the 14 covered group health plan— "(A) as applicable, information collected 15 16 from drug manufacturers by such entity on the 17 total amount of copayment assistance dollars 18 paid, or copayment cards applied, that were 19 funded by the drug manufacturer with respect 20 to the participants and beneficiaries in such 21 plan;

> "(B) a list of each drug covered by such plan or entity providing pharmacy benefit management services that was billed during the re-

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1	porting period, including, with respect to each
2	such drug during the reporting period—
3	"(i) the brand name, generic or non-
4	proprietary name, and National Drug
5	Code;
6	"(ii) the number of participants and
7	beneficiaries for whom the drug was billed
8	during the reporting period, the total num-
9	ber of prescription claims for the drug (in-
10	cluding original prescriptions and refills),
11	and the total number of dosage units of
12	the drug dispensed across the reporting pe-
13	riod;
14	"(iii) for each claim or dosage unit de-
15	scribed in clause (ii), the type of dis-
16	pensing channel used, such as retail, mail
17	order, or specialty pharmacy;
18	"(iv) the wholesale acquisition cost,
19	listed as cost per days supply, cost per dos-
20	age unit, and cost per typical course of
21	treatment (as applicable);
22	"(v) the total out-of-pocket spending
23	by participants and beneficiaries on such
24	drug after application of any benefits
25	under the plan, including participant and

1	beneficiary spending through copayments,
2	coinsurance, and deductibles, but not in-
3	cluding any amounts spent by participants
4	and beneficiaries on drugs not covered
5	under the plan or for which no claim is
6	submitted to the plan; and
7	"(vi) for any drug for which gross
8	spending by the plan exceeded \$10,000
9	and that is one of the 50 prescription
10	drugs for which the group health plan
11	spent the most on prescription drug bene-
12	fits during the reporting period—
13	"(I) a list of all other drugs in
14	the same therapeutic class, including
15	brand name drugs and biological
16	products and generic drugs or bio-
17	similar biological products that are in
18	the same therapeutic class as such
19	drug; and
20	"(II) if applicable, the rationale
21	for preferred formulary placement of
22	such drug in that therapeutic class,
23	selected from a list of standard ra-
24	tionales established by the Secretary;

1	"(C) a list of each therapeutic class of
2	drugs that were dispensed under the health
3	plan during the reporting period, and, with re-
4	spect to each such therapeutic class of drugs,
5	during the reporting period—
6	"(i) total gross spending by the plan,
7	before rebates, fees, alternative discounts,
8	or other remuneration;
9	"(ii) the number of participants and
10	beneficiaries who filled a prescription for a
11	drug in that class;
12	"(iii) if applicable to that class, a de-
13	scription of the formulary tiers and utiliza-
14	tion management mechanisms (such as
15	prior authorization or step therapy) em-
16	ployed for drugs in that class;
17	"(iv) the total out-of-pocket spending
18	by participants and beneficiaries, including
19	participant and beneficiary spending
20	through copayments, coinsurance, and
21	deductibles; and
22	"(v) for each therapeutic class under
23	which 3 or more drugs are included on the
24	formulary of such plan—

1	"(I) the amount received, or ex-
2	pected to be received, by such entity,
3	from an applicable entity, in rebates,
4	fees, alternative discounts, or other
5	remuneration that—
6	"(aa) has been paid, or will
7	be paid, by such an applicable
8	entity for claims incurred during
9	the reporting period; or
10	"(bb) is related to utilization
11	of drugs or drug spending;
12	"(II) the total net spending by
13	the health plan on that class of drugs;
14	and
15	"(III) the net price per typical
16	course of treatment or 30-day supply
17	incurred by the health plan and its
18	participants and beneficiaries, after
19	rebates, fees, alternative discounts, or
20	other remuneration provided by an
21	applicable entity, for drugs dispensed
22	within such therapeutic class during
23	the reporting period;
24	"(D) total gross spending on prescription
25	drugs by the plan during the reporting period,

1 before rebates, fees, alternative discounts, or 2 other remuneration provided by an applicable 3 entity; "(E) the total amount received, or ex-4 5 pected to be received, by the health plan, from 6 an applicable entity, in rebates, fees, alternative 7 discounts, and other remuneration received 8 from any such entities, related to utilization of 9 drug or drug spending under that health plan 10 during the reporting period; 11 "(F) the total net spending on prescription 12 drugs by the health plan during the reporting 13 period; 14 "(G) amounts paid directly or indirectly in 15 rebates, fees, or any other type of compensation 16 (as defined in section 408(b)(2)(B)(ii)(dd)(AA) 17 of the Employee Retirement Income Security 18 of 1974 (29)U.S.C. Act 19 1108(b)(2)(B)(ii)(dd)(A)) to brokers, consult-20 ants, advisors, or any other individual or firm 21 who referred the group health plan's business to 22 the pharmacy benefit manager; and 23 "(H) a summary document that includes 24 such information described in subparagraphs 25 (A) through (G) as the Secretary determines

useful for plan sponsors for purposes of selecting pharmacy benefit management services,
such as an estimated net price to plan sponsor
and participant or beneficiary, a cost per claim,
the fee structure or reimbursement model, and
estimated cost per participant or beneficiary.

# "(2) Supplementary reporting for intracompany prescription drug transactions.—

"(A) IN GENERAL.—An entity providing pharmacy benefit management services under a covered group health plan shall submit, together with the report under paragraph (1), a supplementary report every 6 months to the plan sponsor that includes—

"(i) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan to fill prescriptions at mail order, specialty, or retail pharmacies that are wholly or partially-owned by that entity providing pharmacy benefit management services under such plan, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and copayment incentives funded by an entity

1	providing pharmacy benefit management
2	services;
3	"(ii) the percentage of total prescrip-
4	tions charged to the plan or participants
5	and beneficiaries in the plan, that were
6	dispensed by mail order, specialty, or retail
7	pharmacies that are wholly or partially-
8	owned by the entity providing pharmacy
9	benefit management services; and
10	"(iii) a list of all drugs dispensed by
11	such wholly or partially-owned pharmacy
12	and charged to the plan, or participants
13	and beneficiaries of the plan, during the
14	applicable quarter, and, with respect to
15	each drug—
16	"(I) the amounts charged, per
17	dosage unit, per course of treatment,
18	per 30-day supply, and per 90-day
19	supply, with respect to participants
20	and beneficiaries in the plan, includ-
21	ing amounts charged to the plan and
22	amounts charged to the participants
23	and beneficiaries;
24	"(II) the median amount charged
25	to the plan, per dosage unit, per

1	course of treatment, per 30-day sup-
2	ply, and per 90-day supply, including
3	amounts paid by the participants and
4	beneficiaries, when the same drug is
5	dispensed by other pharmacies that
6	are not wholly or partially-owned by
7	the entity and that are included in the
8	pharmacy network of that plan;
9	"(III) the interquartile range of
10	the costs, per dosage unit, per course
11	of treatment, per 30-day supply, and
12	per 90-day supply, including amounts
13	paid by the participants and bene-
14	ficiaries, when the same drug is dis-
15	pensed by other pharmacies that are
16	not wholly or partially-owned by the
17	entity and that are included in the
18	pharmacy network of that plan;
19	"(IV) the lowest cost, per dosage
20	unit, per course of treatment, per 30-
21	day supply, and per 90-day supply,
22	for such drug, including amounts
23	charged to the plan and participants

and beneficiaries, that is available

1	from any pharmacy included in the
2	network of the plan;
3	"(V) the net acquisition cost per
4	dosage unit and for a 30 day-supply,
5	and the acquisition cost per typical
6	course of treatment, if the drug is
7	subject to a maximum price discount;
8	and
9	"(VI) other information with re-
10	spect to the cost of the drug, as deter-
11	mined by the Secretary, such as aver-
12	age sales price, wholesale acquisition
13	cost, and national average drug acqui-
14	sition cost per dosage unit, per typical
15	course of treatment, or per 30-day
16	supply, for such drug, including
17	amounts charged to the plan and par-
18	ticipants and beneficiaries among all
19	pharmacies included in the network of
20	the plan.
21	"(B) Plans offered by small employ-
22	ERS.—An entity providing pharmacy benefit
23	management services under a group health plan
24	that is not a covered group health plan that
25	conducts transactions with a wholly or partially-

1	owned pharmacy shall submit, together with the
2	report under paragraph (1), a supplementary
3	report every 6 months to the plan sponsor that
4	includes the information described in clauses (i)
5	and (ii) of subparagraph (A).
6	"(3) Privacy requirements.—
7	"(A) RELATIONSHIP TO HIPAA REGULA-
8	TIONS.—Nothing in this section shall be con-
9	strued to modify the requirements for the cre-
10	ation, receipt, maintenance, or transmission of
11	protected health information under the privacy,
12	security, breach notification, and enforcement
13	regulations in parts 160 and 164 of title 45,
14	Code of Federal Regulations (or successor regu-
15	lations).
16	"(B) Requirement.—A report submitted
17	under paragraph (1) or (2) shall contain only
18	summary health information, as defined in sec-
19	tion 164.504(a) of title 45, Code of Federal
20	Regulations (or successor regulations).
21	"(C) CLARIFICATION REGARDING CERTAIN
22	DISCLOSURES OF INFORMATION.—
23	"(i) Reasonable restrictions.—
24	Nothing in this section prevents an entity
25	providing pharmacy benefit management

1	services on behalf of a group health plan
2	from placing reasonable restrictions on the
3	public disclosure of the information con-
4	tained in a report under paragraph (1) or
5	(2).
6	"(ii) Limitations.—An entity pro-
7	viding pharmacy benefit management serv-
8	ices on behalf of a group health plan or
9	group health insurance coverage may not
10	restrict disclosure of such reports to the
11	Department of Health and Human Serv-
12	ices, the Department of Labor, the Depart-
13	ment of the Treasury, or any other Federal
14	agency responsible for enforcement activi-
15	ties under this section for purposes of en-
16	forcement under this section or other ap-
17	plicable law, or to the Comptroller General
18	of the United States in accordance with
19	paragraph (6).
20	"(4) USE AND DISCLOSURE BY PLAN SPON-
21	SORS.—
22	"(A) Prohibition.—A plan sponsor may
23	not—
24	"(i) fail or refuse to hire, or dis-
25	charge, any employee, or otherwise dis-

1	criminate against any employee with re-
2	spect to the compensation, terms, condi-
3	tions, or privileges of employment of the
4	employee, because of information sub-
5	mitted under paragraph (1) or (2) attrib-
6	uted to the employee or a dependent of the
7	employee; or
8	"(ii) limit, segregate, or classify the
9	employees of the employer in any way that
10	would deprive or tend to deprive any em-
11	ployee of employment opportunities or oth-
12	erwise adversely affect the status of the
13	employee as an employee, because of infor-
14	mation submitted under paragraph (1) or
15	(2) attributed to the employee or a depend-
16	ent of the employee.
17	"(B) DISCLOSURE AND REDISCLOSURE.—
18	A plan sponsor shall not disclose the informa-
19	tion received under paragraph (1) or (2) ex-
20	cept—
21	"(i) to an occupational or other health
22	researcher if the research is conducted in
23	compliance with the regulations and pro-
24	tections provided for under part 46 of title

1	45, Code of Federal Regulations (or suc-
2	cessor regulations);
3	"(ii) in response to an order of a
4	court, except that the plan sponsor may
5	disclose only the information expressly au-
6	thorized by such order;
7	"(iii) to the Department of Health
8	and Human Services, the Department of
9	Labor, the Department of the Treasury, or
10	other Federal agency responsible for en-
11	forcement activities under this section; or
12	"(iv) to a contractor or agent for pur-
13	poses of health plan administration, if such
14	contractor or agent agrees, in writing, to
15	abide by the same use and disclosure re-
16	strictions as the plan sponsor.
17	"(C) Relationship to hipaa regula-
18	TIONS.—With respect to the regulations pro-
19	mulgated by the Secretary of Health and
20	Human Services under part C of title XI of the
21	Social Security Act (42 U.S.C. 1320d et seq.)
22	and section 264 of the Health Insurance Port-
23	ability and Accountability Act of 1996 (42
24	U.S.C. 1320d–2), subparagraph (B) does not
25	prohibit a covered entity (as defined for pur-

poses of such regulations) from any use or disclosure of health information that is authorized for the covered entity under such regulations. The previous sentence does not affect the authority of such Secretary to modify such regulations.

## "(D) Enforcement.—

"(i) IN GENERAL.—The powers, procedures, and remedies provided in section 207 of the Genetic Information Non-discrimination Act (42 U.S.C. 2000ff–6) to a person alleging a violation of title II of such Act shall be the powers, procedures, and remedies this subparagraph provides for any person alleging a violation of this paragraph.

"(ii) Prohibition against retaliation.—No person shall discriminate against any individual because such individual has opposed any act or practice made unlawful by this paragraph or because such individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under this paragraph. The rem-

edies and procedures otherwise provided
for under this subparagraph shall be available to aggrieved individuals with respect
to violations of this clause.

"(5) Reporting with respect to group Health plans offered by small employers.—
For plan years beginning on or after January 1, 2025, not less frequently than annually, an entity providing pharmacy benefit management services on behalf of a group health plan that is not a covered group health plan shall submit to the plan sponsor of such group health plan a report in accordance with this paragraph, and make such report available to the plan sponsor in a machine-readable format. Each such report shall include, with respect to the applicable group health plan, the information described in subparagraphs (A), (D), (E), (F), (G), and (H) of paragraph (1).

"(6) SUBMISSIONS TO GAO.—An entity providing pharmacy benefit management services on behalf of a group health plan shall submit to the Comptroller General of the United States each of the first 2 reports submitted to a plan sponsor under paragraph (1) or (5) with respect to such plan, and other such reports as requested, in accordance with

the privacy requirements under paragraph (3), and such other information that the Comptroller General determines necessary to carry out the study under section 2(f) of the Pharmacy Benefit Manager Reform Act.

## "(7) STANDARD FORMATS.—

"(A) IN GENERAL.—Not later than June 1, 2024, the Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall specify, through rulemaking, standard formats for health insurance issuers and entities providing pharmacy benefit management services to submit reports required under this subsection.

"(B) LIMITED FORM OF REPORT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of Labor shall define through rulemaking a limited form of the reports under paragraphs (1) and (2) required to be submitted to plan sponsors who also are drug manufacturers, drug wholesalers, entities providing pharmacy benefit management services, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.

1	"(c) Limitations on Spread Pricing.—
2	"(1) In general.—A group health plan shall
3	not charge participants and beneficiaries, and an en-
4	tity providing pharmacy benefit management serv-
5	ices under such a plan shall not charge the plan or
6	participants and beneficiaries, a price for a prescrip-
7	tion drug that exceeds the price paid to the phar-
8	macy for such drug, excluding penalties paid by the
9	pharmacy (as described in paragraph (2)) to such
10	plan or entity.
11	"(2) Rule of construction.—For purposes
12	of paragraph (1), penalties paid by pharmacies in-
13	clude only the following:
14	"(A) A penalty paid if an original claim for
15	a prescription drug was submitted fraudulently
16	by the pharmacy to the plan or entity.
17	"(B) A penalty paid if the original claim
18	payment made by the plan, issuer, or entity to
19	the pharmacy was inconsistent with the reim-
20	bursement terms in any contract between the
21	pharmacy and the plan or entity.
22	"(C) A penalty paid if the pharmacist serv-
23	ices billed to the plan or entity were not ren-
24	dered by the pharmacy.
25	"(d) Full Repare Pass-Through to Plan —

1	"(1) In general.—For plan years beginning
2	on or after January 1, 2025, a third-party adminis-
3	trator of a group health plan or an entity providing
4	pharmacy benefit management services under such
5	health plan shall—
6	"(A) remit 100 percent of rebates, fees, al-
7	ternative discounts, and other remuneration re-
8	ceived from any applicable entity that are re-
9	lated to utilization of drugs under such health
10	plan, to the group health plan; and
11	"(B) ensure that any contract entered into
12	by such third-party administrator or entity pro-
13	viding pharmacy benefit management services
14	with an applicable entity remit 100 percent of
15	rebates, fees, alternative discounts, and other
16	remuneration received to the third-party admin-
17	istrator or entity providing pharmacy benefit
18	management services.
19	"(2) Form and manner of remittance.—
20	Such rebates, fees, alternative discounts, and other
21	remuneration shall be—
22	"(A) remitted to the group health plan in
23	a timely fashion after the period for which such
24	rebates, fees, alternative discounts, or other re-

1	muneration is calculated, and in no case later
2	than 90 days after the end of such period;
3	"(B) fully disclosed and enumerated to the
4	group health plan sponsor, as described in para-
5	graphs (1) and (4) of subsection (b);
6	"(C) available for audit by the plan spon-
7	sor, or a third-party designated by a plan spon-
8	sor not less than once per plan year; and
9	"(D) returned to the issuer or entity pro-
10	viding pharmaceutical benefit management
11	services by the group health plan if audits by
12	such entity indicate that the amounts received
13	are incorrect after such amounts have been paid
14	to the group health plan.
15	"(3) Audit of Rebate Contracts.—A third-
16	party administrator of a group health plan or an en-
17	tity providing pharmacy benefit management serv-
18	ices under such health plan shall make rebate con-
19	tracts with rebate aggregators or drug manufactur-
20	ers available for audit by such plan sponsor or des-
21	ignated third-party, subject to confidentiality agree-
22	ments to prevent re-disclosure of such contracts.
23	"(4) Auditors.—The applicable plan sponsor
24	may select an auditor for purposes of carrying out
25	audits under paragraphs (2)(C) and (3).

1 "(5) RULE OF CONSTRUCTION.—Nothing in 2 this subsection shall be construed to prohibit pay-3 ments to entities offering pharmacy benefit manage-4 ment services for bona fide services using a fee 5 structure not contemplated by this subsection, pro-6 vided that such fees are transparent to group health 7 plans.

## "(e) Enforcement.—

- "(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor and the Secretary of Health and Human Services, shall enforce this section.
- "(2) Failure to provide timely information.—A health insurance issuer or an entity providing pharmacy benefit management services that violates subsection (a) or fails to provide information required under subsection (b); a group health plan or entity providing pharmacy benefit management services that violates subsection (c); or a third-party administrator of a group health plan or an entity providing pharmacy benefit management services that violates subsection (d) shall be subject to a civil monetary penalty in the amount of \$10,000 for each day during which such violation continues or such information is not disclosed or reported.

"(3) False information.—An entity pro-viding pharmacy benefit management services, or drug manufacturer that knowingly provides false in-formation under this section shall be subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalty shall be in addition to other pen-alties as may be prescribed by law.

- "(4) PROCEDURE.—The provisions of section 1128A of the Social Security Act, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1128A of the Social Security Act.
- "(5) WAIVERS.—The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with this section.
- "(f) Rule of Construction.—Nothing in this section shall be construed to permit a group health plan or other entity to restrict disclosure to, or otherwise limit the

1	access of, the Department of the Treasury to a report de-
2	scribed in subsection (b)(1) or information related to com-
3	pliance with subsection (a) by such plan or entity.
4	"(g) Definitions.—In this section—
5	"(1) the term 'applicable entity' means—
6	"(A) a drug manufacturer, distributor,
7	wholesaler, rebate aggregator (or other pur-
8	chasing entity designed to aggregate rebates)
9	group purchasing organization, or associated
10	third party;
11	"(B) any subsidiary, parent, affiliate, or
12	subcontractor of a group health plan, health in-
13	surance issuer, entity that provides pharmacy
14	benefit management services on behalf of such
15	a plan or issuer, or any entity described in sub-
16	paragraph (A); or
17	"(C) such other entity as the Secretary,
18	the Secretary of Health and Human Services.
19	and the Secretary of Labor may specify through
20	rulemaking;
21	"(2) the term 'covered group health insurance
22	coverage' means health insurance coverage offered in
23	connection with a group health plan maintained by
24	a large employer.

- 1 "(3) the term 'covered group health plan' 2 means a group health plan maintained by a large 3 employer;
  - "(4) the term 'gross spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of manufacturer rebates, fees, alternative discounts, or other remuneration;
  - "(5) the term 'large employer' means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 50 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year;
  - "(6) the term 'net spending', with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of manufacturer rebates, fees, alternative discounts, or other remuneration;

1	"(7) the term 'plan sponsor' has the meaning
2	given such term in section 3(16)(B) of the Employee
3	Retirement Income Security Act of 1974 (29 U.S.C.
4	1002(16)(B));
5	"(8) the term 'remuneration' has the meaning
6	given such term by the Secretary, the Secretary of
7	Labor, and the Secretary of Health and Human
8	Services, through notice and comment rulemaking;
9	"(9) the term 'small employer' means, in con-
10	nection with a group health plan with respect to a
11	calendar year and a plan year, an employer who em-
12	ployed an average of at least 1 but not more than
13	49 employees on business days during the preceding
14	calendar year and who employs at least 1 employee
15	on the first day of the plan year; and
16	"(10) the term 'wholesale acquisition cost' has
17	the meaning given such term in section
18	1847A(c)(6)(B) of the Social Security Act (42
19	U.S.C. $1395w-3a(c)(6)(B)$ ).".
20	(2) CLERICAL AMENDMENT.—The table of sec-
21	tions for subchapter B of chapter 100 of the Inter-
22	nal Revenue Code of 1986 is amended by adding at
23	the end the following new item:

"Sec. 9826. Oversight of entities that provide pharmacy benefit management services.".

24 (d) Funding.—

- 1 (1) For purposes of carrying out the amend-2 ments made by subsection (a), there are appro-3 priated to the Centers for Medicare & Medicaid 4 Services, out of amounts in the Treasury not other-5 wise appropriated, \$80,000,000 for fiscal year 2024.
- 6 (2) For purposes of carrying out the amend7 ments made by subsection (b), there are appro8 priated to the Department of Labor, out of amounts
  9 in the Treasury not otherwise appropriated,
  10 \$43,750,000 for fiscal year 2024.
- 11 (e) ASPE STUDY.—The Assistant Secretary for 12 Planning and Evaluation of the Department of Health and Human Services shall conduct or commission a study on how the United States health care market would be impacted by potential regulatory changes disallowing manufacturer rebates in the manner and to the extent allowed 16 17 on the date of enactment of this Act, with a focus on the impact to stakeholders in the commercial insurance mar-18 ket, and, not later than 1 year after the date of enactment 19 20 of this Act, submit a report to Congress on the results 21 of such study. Such study and report shall consider the
- 23 (1) The impact on the impact of making no 24 such regulatory changes, as well as potential behav-25 ioral changes by plan sponsors, members, and phar-

following:

- 1 maceutical manufacturers, such as tighter 2 formularies, changes to price concessions, changes in 3 utilization, if such regulatory changes are made.
  - (2) The mechanics needed in the pharmaceutical supply chain (whether existing or not) to move a manufacturer rebate to the point of sale.
  - (3) The feasibility of a partial point-of-sale manufacturer rebate versus a full point-of-sale manufacturer rebate.
  - (4) The impact on patient out-of-pocket costs, premiums, and other cost-sharing.
  - (5) Possible behavioral changes by other third parties in the pharmaceutical supply chain including drug manufacturer, distributor, wholesaler, rebate aggregators, pharmacy services administrative organizations, or group purchasing organizations.
  - (6) Behavioral changes between entities that contract with pharmaceutical manufacturers and pharmaceutical supply chain.
  - (7) Alternative price negotiation mechanisms, including the impact of the Act of June 19, 1936 (commonly known as the "Robinson–Patman Act"; 49 Stat. 1526, chapter 592; 15 U.S.C. 13a et seq.), and the amendments made by that Act, on drug pricing negotiations.

1	(8) The impact on pharmacies, including phar-
2	macy rebates, pharmacy fees, and dispensing chan-
3	nels.
4	(f) GAO Study.—
5	(1) In general.—Not later than January 1,
6	2029, the Comptroller General of the United States
7	shall report to Congress on—
8	(A) pharmacy networks of group health
9	plans, health insurance issuers, and entities
10	providing pharmacy benefit management serv-
11	ices under such group health plan or group or
12	individual health insurance coverage, including
13	networks that have pharmacies that are under
14	common ownership (in whole or part) with
15	group health plans, health insurance issuers, or
16	entities providing pharmacy benefit manage-
17	ment services or pharmacy benefit administra-
18	tive services under group health plan or group
19	or individual health insurance coverage;
20	(B) as it relates to pharmacy networks
21	that include pharmacies under common owner-
22	ship described in subparagraph (A)—
23	(i) whether such networks are de-
24	signed to encourage participants and bene-
25	ficiaries of a plan or coverage to use such

1	pharmacies over other network pharmacies
2	for specific services or drugs, and if so, the
3	reasons the networks give for encouraging
4	use of such pharmacies; and
5	(ii) whether such pharmacies are used
6	by participants and beneficiaries dispropor-
7	tionately more in the aggregate or for spe-
8	cific services or drugs compared to other
9	network pharmacies;
10	(C) whether group health plans and health
11	insurance issuers offering group or individual
12	health insurance coverage have options to elect
13	different network pricing arrangements in the
14	marketplace with entities that provide phar-
15	macy benefit management services, the preva-
16	lence of electing such different network pricing
17	arrangements;
18	(D) pharmacy network design parameters
19	that encourage participants and beneficiaries in
20	the plan or coverage to fill prescriptions at mail
21	order, specialty, or retail pharmacies that are
22	wholly or partially-owned by that issuer or enti-
23	ty; and
24	(E) the degree to which mail order, spe-
25	cialty, or retail pharmacies that dispense pre-

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scription drugs to participants and beneficiaries in a group health plan or health insurance coverage that are under common ownership (in whole or part) with group health plans, health insurance issuers, or entities providing pharmacy benefit management services or pharmacy benefit administrative services under group health plan or group or individual health insurance coverage receive reimbursement that is greater than the median price charged to the group health plan or health insurance issuer when the same drug is dispensed to participants and beneficiaries in the plan or coverage by other pharmacies included in the pharmacy network of that plan, issuer, or entity that are not wholly or partially owned by the health insurance issuer or entity providing pharmacy benefit management services.

- (2) REQUIREMENT.—In carrying out paragraph (1), the Comptroller General of the United States shall not disclose—
  - (A) information that would allow for identification of a specific individual, plan sponsor, health insurance issuer, plan, or entity pro-

I	viding pharmacy benefit management services.
2	or
3	(B) commercial or financial information
4	that is privileged or confidential.
5	(3) Definitions.—In this subsection, the
6	terms "group health plan", "health insurance cov-
7	erage", and "health insurance issuer" have the
8	meanings given such terms in section 2791 of the
9	Public Health Service Act (42 U.S.C. 300gg-91).

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